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(54) **APPARATUS AND METHOD FOR SUTURING BODY LUMENS**

(75) Inventors: **Aaron M. Fortson**, Freemont, CA (US); **Douglas H. Mehl**, Redwood City, CA (US); **Dinorah Merrill**, Salida, CA (US); **David J. Milazzo**, Santa Clara, CA (US)

(73) Assignee: **Abbott Cardiovascular Systems, Inc.**, Santa Clara, CA (US)

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See application file for complete search history.

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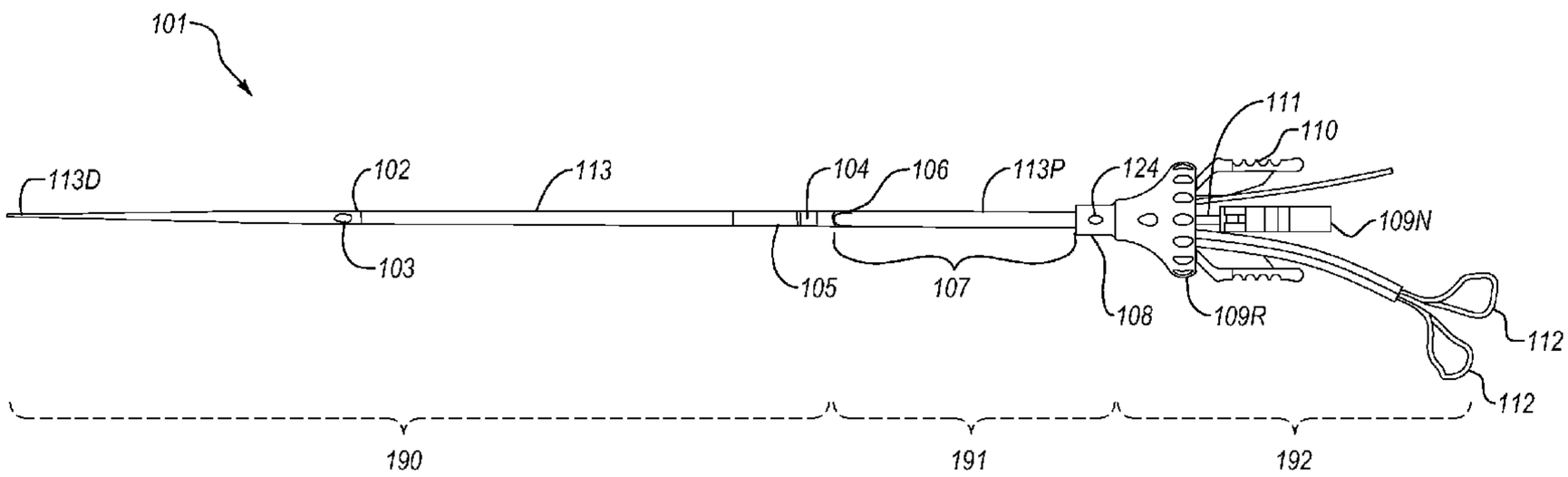
Primary Examiner — Julian W Woo
Assistant Examiner — Lucas Paez
(74) *Attorney, Agent, or Firm* — Workman Nydegger; Randy Shen

(57) **ABSTRACT**

An apparatus for suturing body lumens is provided. The apparatus includes a flexible elongated member that has a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member further includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member into a body lumen. The apparatus further includes needles disposed within and advanceable from the needle lumens. The apparatus also includes a handle disposed at the proximal end of the elongated member. The handle is operable to retract the needles through the needle lumens toward the handle at the proximal end.

18 Claims, 6 Drawing Sheets



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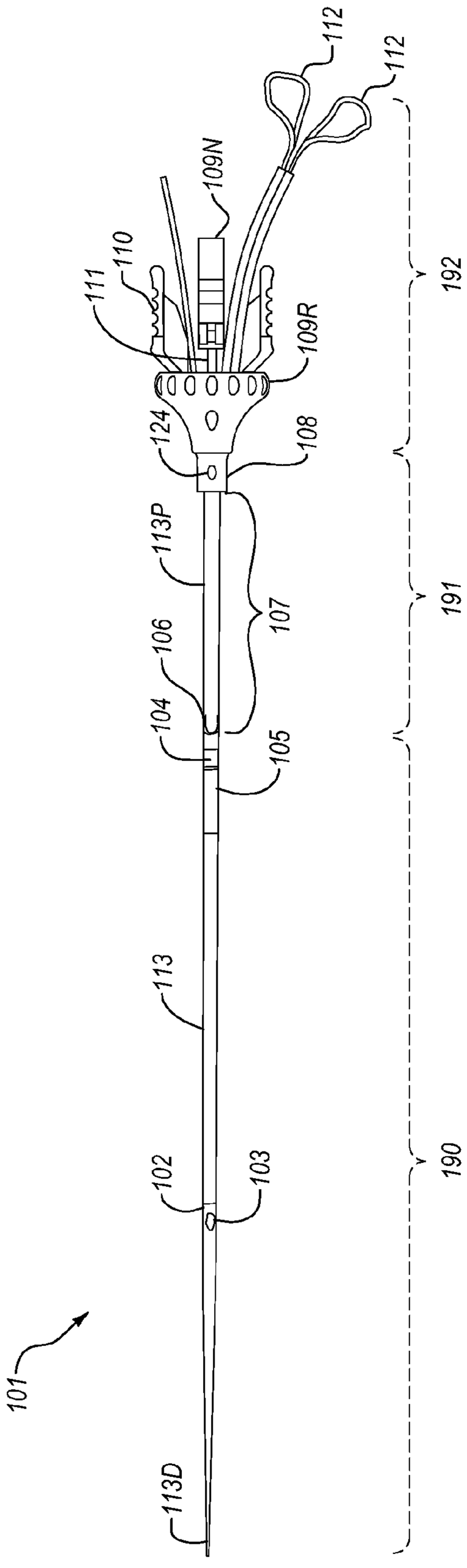
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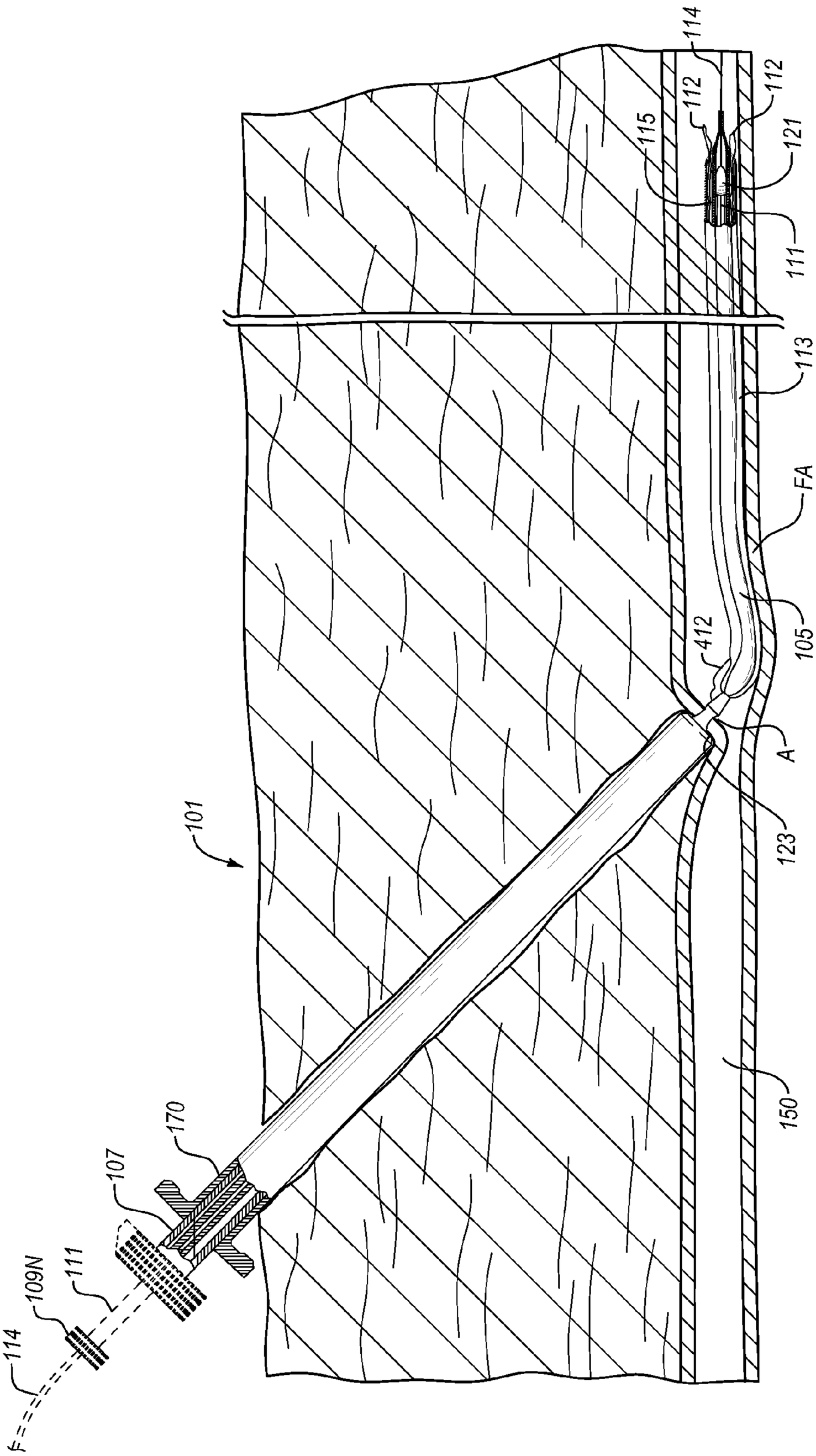
Fig. 1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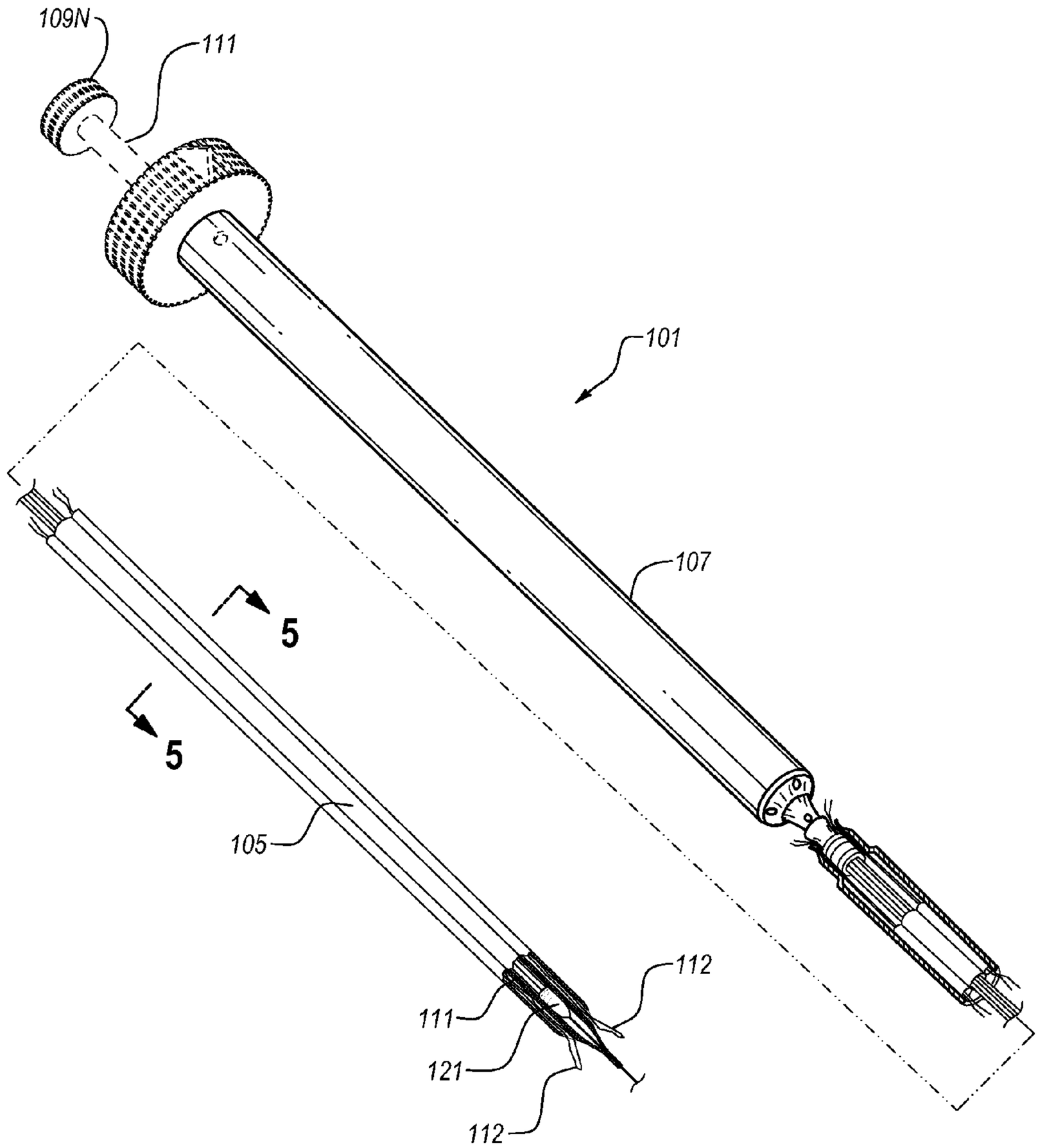

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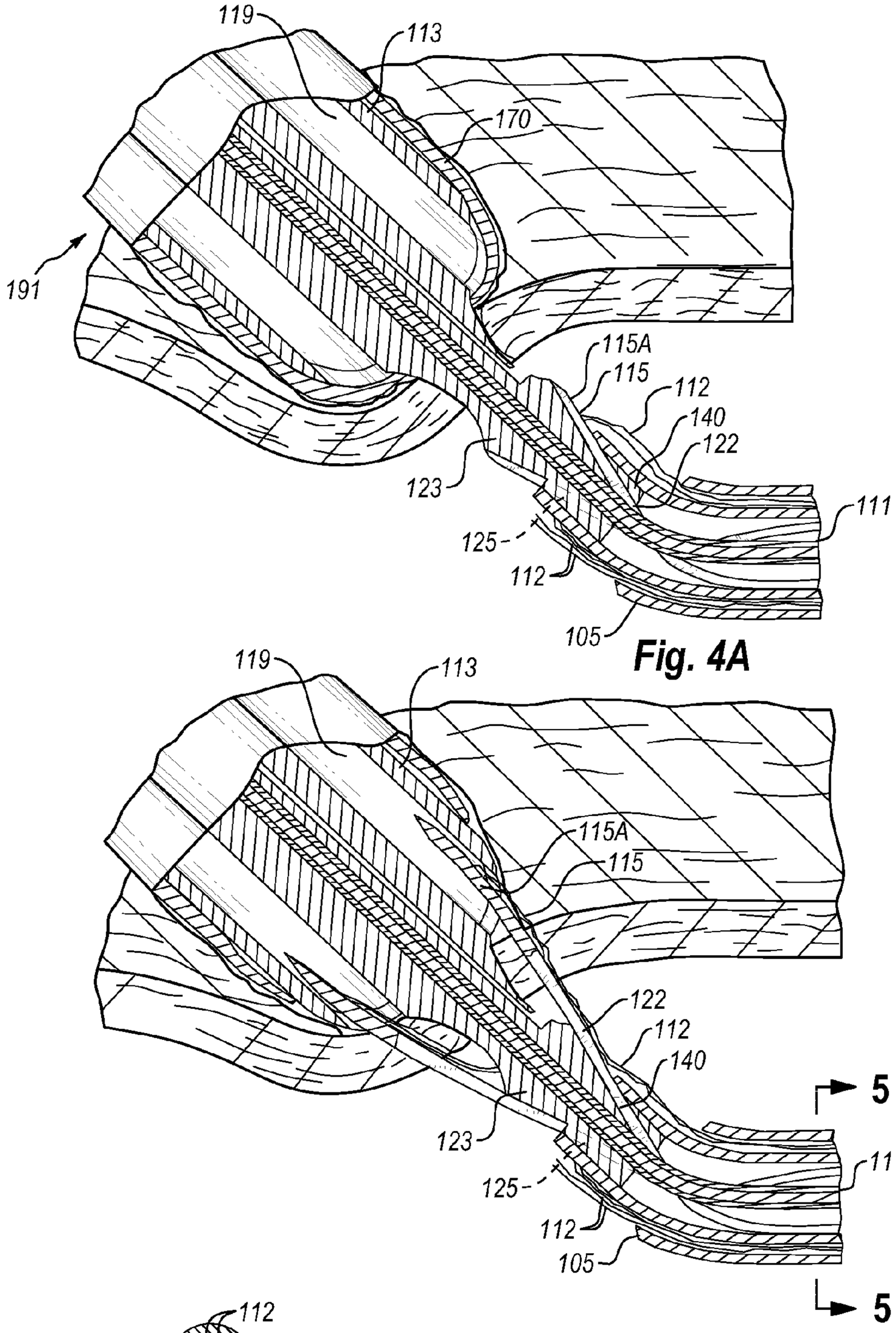
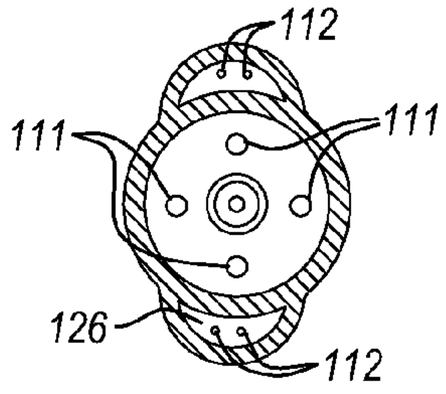


Fig. 4A

Fig. 4B



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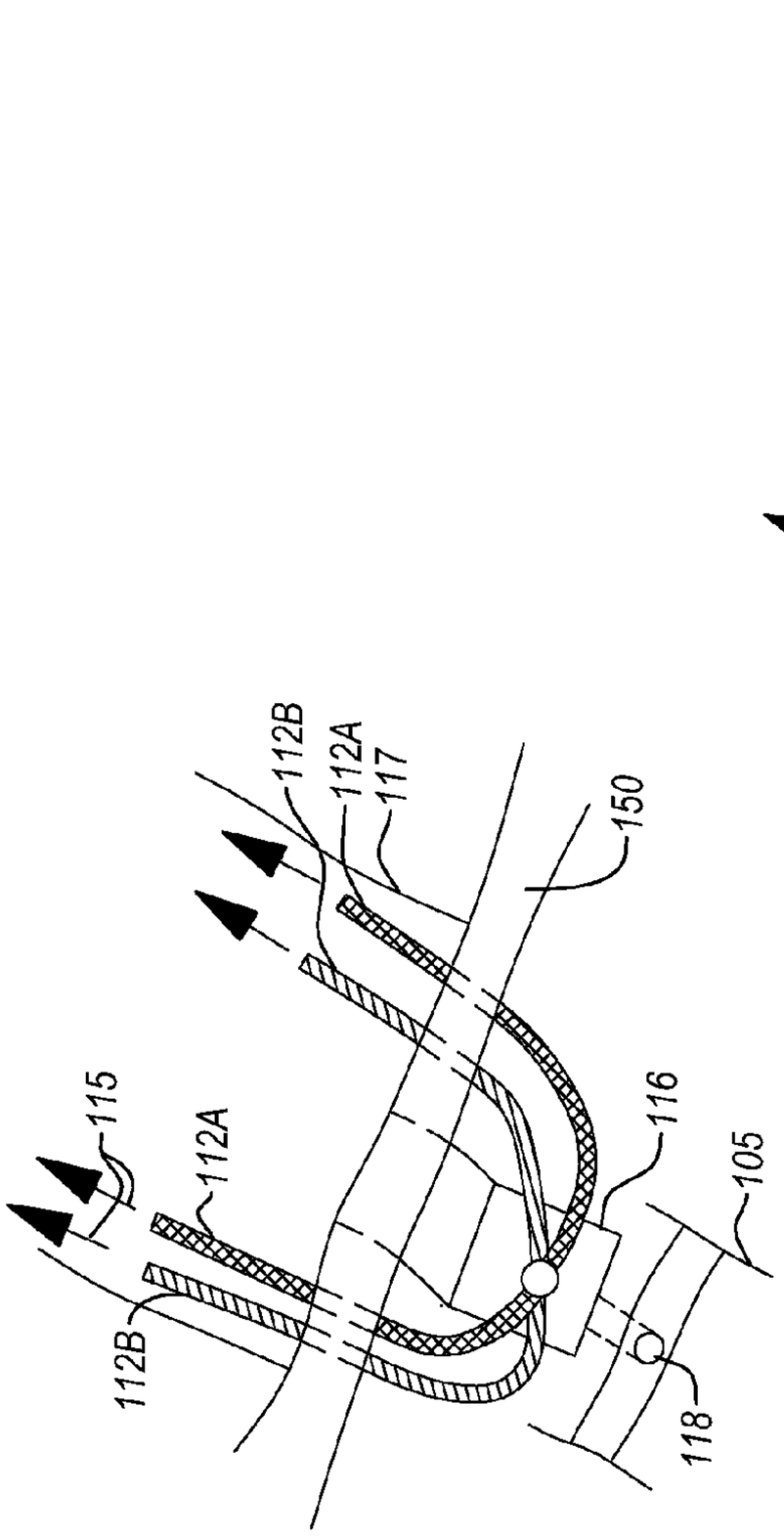

Fig. 6B

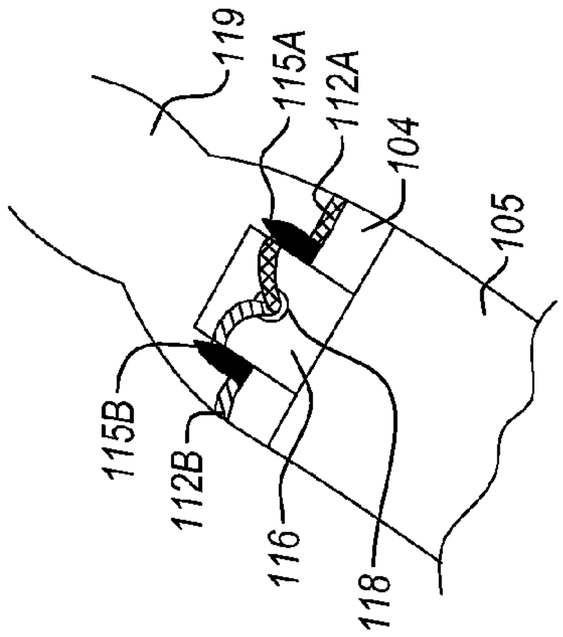

Fig. 6A

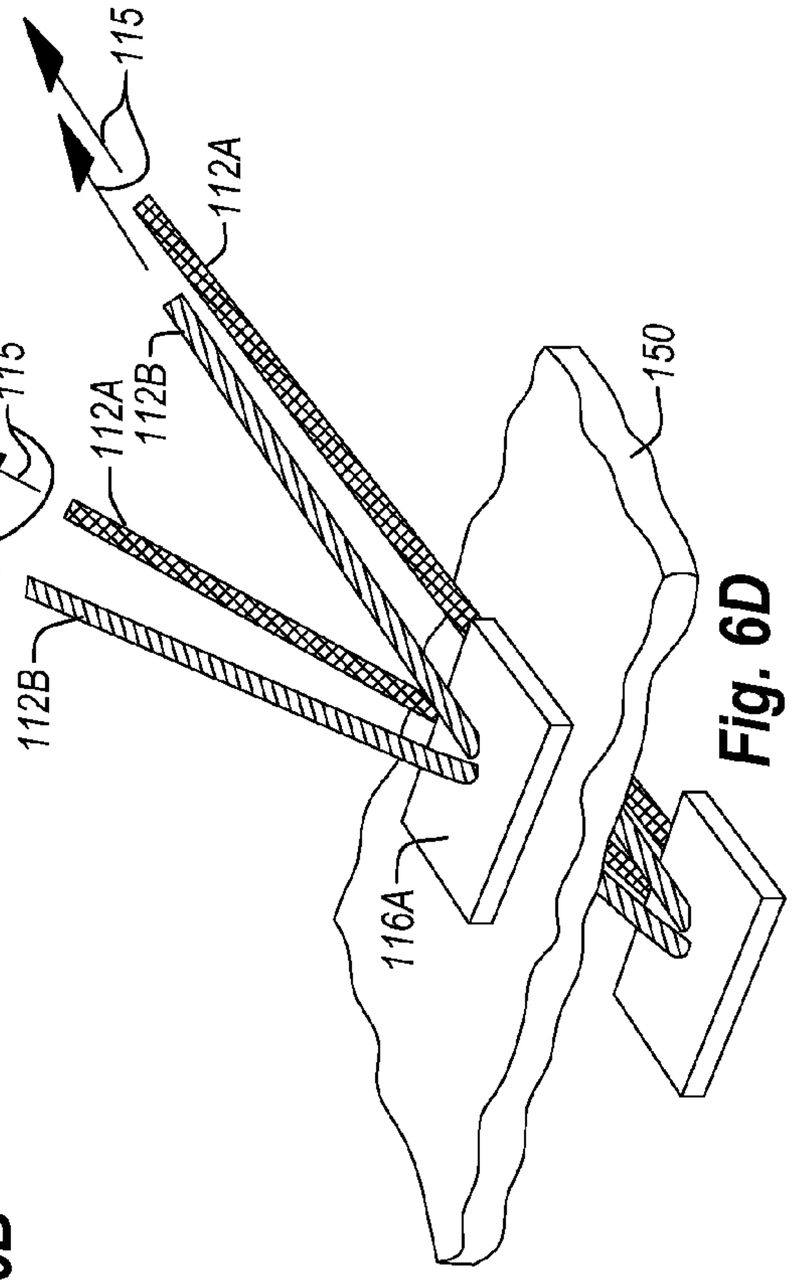

Fig. 6D

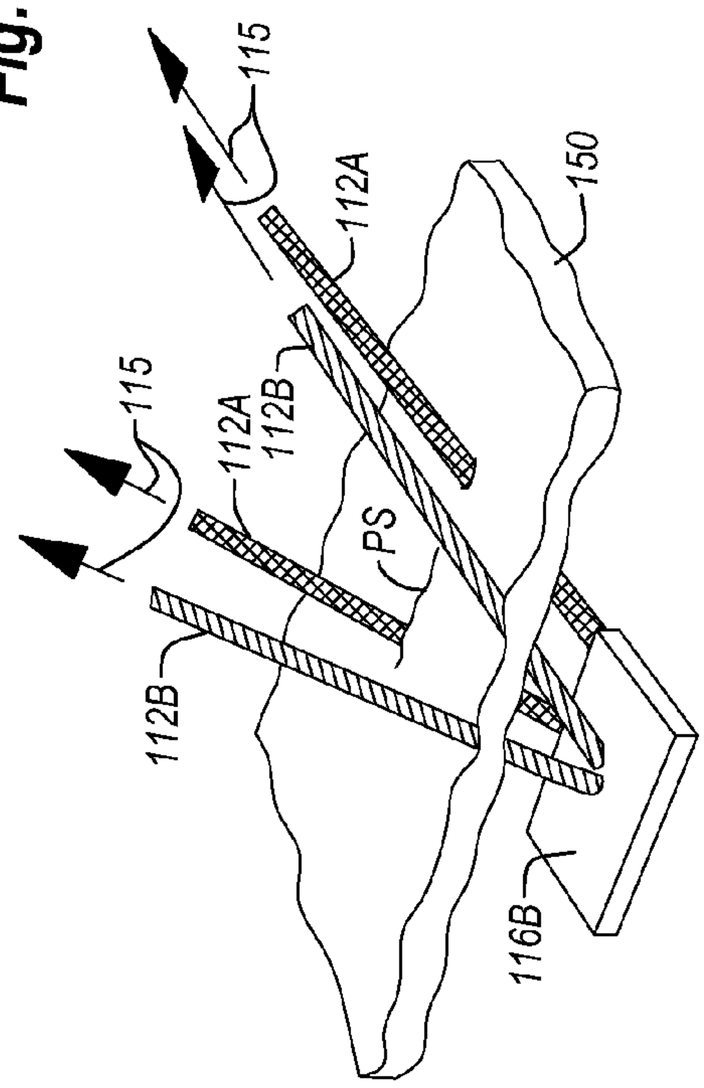

Fig. 6C

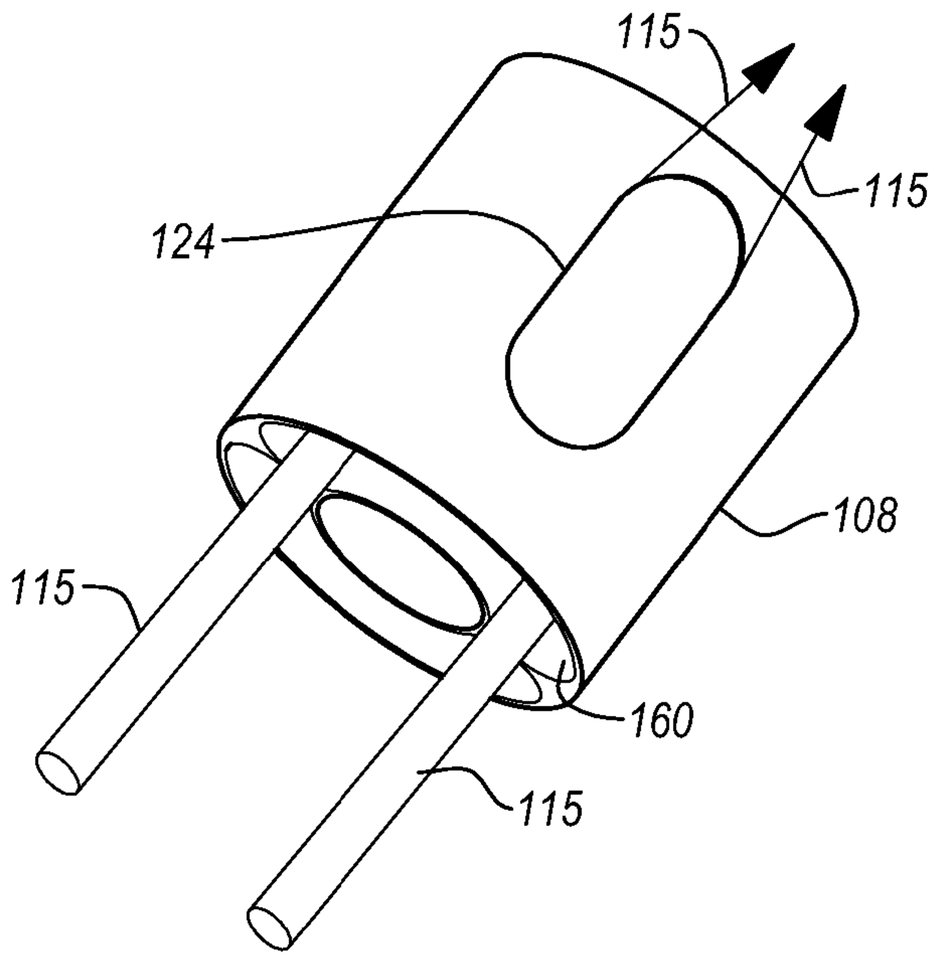

Fig. 7

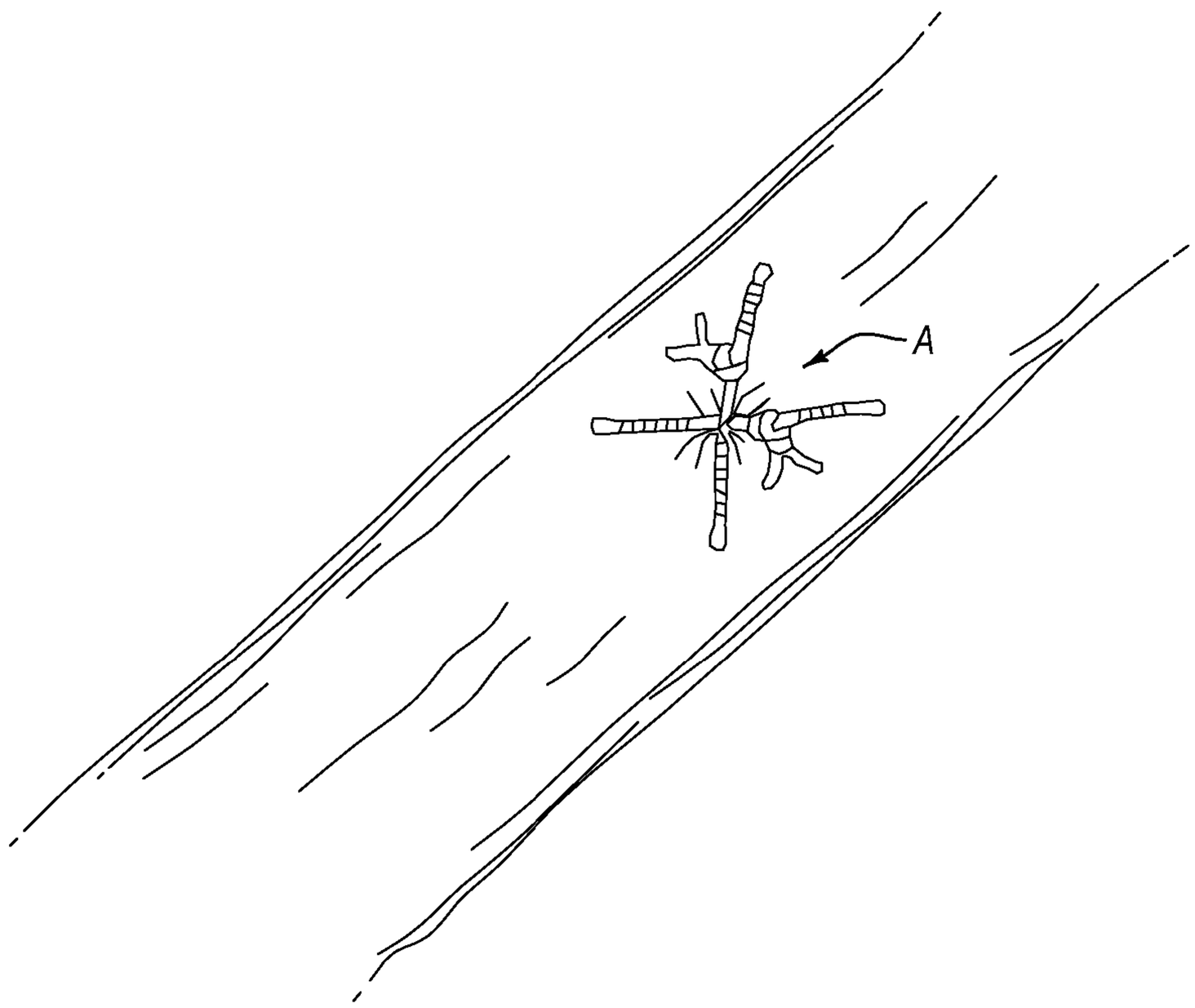

Fig. 8

APPARATUS AND METHOD FOR SUTURING BODY LUMENS

BACKGROUND

1. Technical Field

The present disclosure relates generally to techniques and devices for closing openings in body lumens. More particularly, the present disclosure relates to systems, devices, and methods for percutaneous closure of arterial and venous puncture sites, which are usually accessed through a tissue tract.

2. The Relevant Technology

Many diagnostic and interventional vascular procedures are now performed translumenally. A catheter is introduced to the vascular system at a convenient access location and guided through the vascular system to a target location using established techniques. Such procedures require vascular access, which is usually established using the well-known Seldinger technique. Vascular access is generally provided through an introducer sheath, which is positioned to extend from outside the patient's body into the vascular lumen. When vascular access is no longer required, the introducer sheath is removed and bleeding at the puncture site is stopped using one of a variety of methods.

One method for providing hemostasis (the cessation of bleeding) is to apply external force near and upstream from the puncture site, typically by manual compression. This approach suffers from a number of disadvantages. For example, the manual compression procedure is time consuming, frequently requiring 30 or more minutes of compression before hemostasis is achieved. Additionally, such compression techniques rely on clot formation, which can be delayed until anticoagulants used in vascular therapy procedures (such as for heart attacks, stent deployment, non-optical PTCA results, and the like) wear off. The anticoagulants may take two to four hours to wear off, thereby increasing the time required before completion of the manual compression procedure.

Further, the manual compression procedure is uncomfortable for the patient and frequently requires analgesics to be tolerable. Moreover, the application of excessive pressure can at times totally occlude the underlying blood vessel, resulting in ischemia and/or thrombosis. Following manual compression, the patient typically remains recumbent from four to twelve hours or more under close observation to assure continued hemostasis. During this time, renewed bleeding may occur, resulting in blood loss through the tract, hematoma and/or pseudo-aneurysm formation, as well as arteriovenous fistula formation. These complications may require blood transfusions and/or surgical intervention.

The incidence of complications from the manual compression procedure increases when the size of the introducer sheath grows larger, and/or when the patient is anticoagulated. The compression technique for arterial closure can be risky, and is expensive and onerous to the patient. Although using highly trained individuals can reduce the risk of complications, dedicating such personnel to this task is both expensive and inefficient. Nonetheless, as the number and efficacy of translumenally performed diagnostic and interventional vascular procedures increases, the number of patients requiring effective hemostasis for a vascular puncture continues to increase.

To overcome the problems associated with manual compression, bioabsorbable sealing bodies have been used. Generally, a thrombogenic and bioabsorbable material, such as collagen, is placed at the superficial wall of the body lumen over the puncture site. While potentially effective, this approach suffers from a number of drawbacks. For example, bioabsorbable sealing bodies may lack a solid mechanical attachment of the sealing body to the tissue. Due to the lack of a solid mechanical attachment, the sealing body can wander within the tissue tract or move out of the puncture site, thus causing late bleeds. Conversely, if the sealing body wanders and intrudes too far into the body lumen, due to the lack of a solid mechanical attachment, intravascular clots and/or collagen pieces with thrombus attached can form and embolize downstream, causing vascular occlusion.

BRIEF SUMMARY

This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter. Embodiments described herein provide systems, methods, and devices for closing an opening in tissue. Embodiments can be configured to close an opening within a body lumen.

For instance, in one embodiment, an apparatus for suturing a body lumen includes a flexible elongated member that has a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member further includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member into a body lumen. The apparatus further includes multiple different needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion. The apparatus also includes a handle disposed at the proximal end of the elongated member. The handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

In another embodiment, a method is provided for suturing an opening in a body lumen. The method includes providing a body lumen suturing device, where the body lumen suturing device includes a flexible elongated member that has a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member. The body lumen suturing device further includes needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion, as well as a handle disposed at the proximal end of the elongated member, where the handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

In yet another embodiment, a body lumen suturing device includes a flexible elongated member having a proximal end, a distal end, a central passage and multiple needle lumens

extending from the proximal end toward the distal end. The flexible elongated member further includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member. The elongated member also includes a crimp ring configured to hold pledgets in place at the proximal end of the needle lumens in the elongated member. The device also includes needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion, as well as one or more pledgets stored at the proximal end of the needle lumens in the elongated member. The pledgets include holes through which the sutures may be pulled. The device also includes a handle disposed at the proximal end of the elongated member, where the handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

Additional features and advantages will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the teachings herein. Features and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. Features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

To further clarify the above and other advantages and features of embodiments of the present invention, a more particular description of embodiments of the present invention will be rendered by reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. The invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** illustrates a side view of an example embodiment of the suturing device.

FIG. **2** illustrates insertion of the elongate member and barrel portion.

FIG. **3** is a perspective view of an example embodiment of a suturing device.

FIG. **4**A is a detailed view of the distal end of the guide body of the suturing device of FIG. **2**, shown with the needles retracted fully within the guide body.

FIG. **4**B is a detailed view similar to FIG. **4**A, except that the needles have been partially deployed.

FIG. **5**. is a cross-sectional view of the device of FIGS. **4**A and **4**B, taken along line **3-3** of FIG. **4**B.

FIGS. **6**A-**6**D illustrate various embodiments of the suturing device that implement pledgets.

FIG. **7** illustrates a barrel comprising semi-circular openings on the distal end configured to draw the needles toward a narrow exit hole on the proximal end of the barrel.

FIG. **8** illustrates the X-pattern of the tied suture applied by the suturing device.

DETAILED DESCRIPTION

Embodiments described herein provide systems, methods, and devices for closing an opening in tissue. Embodiments can be configured to close an opening within a body lumen. For instance, in one embodiment, an apparatus for suturing a body lumen includes a flexible elongated member that has a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member further includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member into a body lumen. The apparatus further includes multiple different needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion. The apparatus also includes a handle disposed at the proximal end of the elongated member. The handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

In another embodiment, a method is provided for suturing an opening in a body lumen. The method includes providing a body lumen suturing device, where the body lumen suturing device includes a flexible elongated member that has a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member. The body lumen suturing device further includes needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion, as well as a handle disposed at the proximal end of the elongated member, where the handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

In yet another embodiment, a body lumen suturing device includes a flexible elongated member having a proximal end, a distal end, a central passage and multiple needle lumens extending from the proximal end toward the distal end. The flexible elongated member further includes an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion that includes corresponding needle lumens on the proximal end of the elongated member. The elongated subsection provides sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member. The elongated member also includes a crimp ring configured to hold pledgets in place at the proximal end of the needle lumens in the elongated member. The device also includes needles disposed within and advanceable from the needle lumens in the flexible elongated member across the elongated subsection to corresponding needle lumens in the barrel portion, as well as one or more pledgets stored at the proximal end of the needle lumens in the elongated member. The pledgets include holes through which the sutures may be pulled. The device also includes a handle disposed at the proximal end of the elongated member, where the handle is operable to retract the needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end.

As used herein, the term "distal" is generally defined as in the direction of the patient, or away from a user of a device, or in a downstream direction relative to a forward flow of blood. In the context of a medical device intervention with or through a vessel wall, "distal" herein refers to the interior or the lumen side of the vessel wall.

Conversely, "proximal" generally means away from the patient, or toward the user, or in an upstream direction relative to a forward flow of blood. In the context of a medical device intervention with or through a vessel wall, "proximal" herein refers to the exterior or outer side of the vessel wall.

Additionally, "oblong" is herein intended to mean oval, elliptical, or otherwise having a generally rounded shape that is not perfectly circular. In particular, the term describes the shape of a tubular graft end cut at an acute angle relative to the plane perpendicular to the tissue walls defining the graft.

The term "hemostasis" is herein used to mean the arrest of bleeding or substantially blocking flow of blood outwardly from a vessel lumen while the vessel lumen is pressurized or sustaining physiological blood flow. This amount of blockage or occlusion to flow is further defined such that the blood loss which is experienced is less than an amount which would affect procedural methods or outcomes according to a physician user of a device of ordinary skill in the art. In other words, "hemostasis" is not intended to mean only "total hemostasis" such that there is a total lack of blood loss. Rather, the term is used to also mean "procedural hemostasis" as a relative term in its use among physicians of ordinary skill.

Similarly, "occlusion," "occlude," "blockage," "block . . . plugging", "block," or variations thereof are all terms which are herein intended to have a procedurally relevant definition in the context of their use. For instance, an aperture is "occluded" although there is some measurable flow therethrough, but that flow is so low such that the intended procedural benefit of occlusion is at least partially achieved. Certainly, such terms also properly include within their scope a "total effect" definition, as well.

The term "perfusion" is herein used to mean the flow of blood or other unit of perfusate (the fluid used for perfusion) per unit volume of tissue. Physiological perfusion refers to the amount of blood flow present when the body is functioning normally. For example, physiological perfusion usually prevents clinically significant ST elevations which is one of the most sensitive indicators of inadequate perfusion. Adequate perfusion refers to the amount of blood flow that avoids the clinical requirement of transfusing the patient or that is needed to prevent tissue necrosis distal to the aperture in the blood vessel.

The term "suturing" is herein intended to include the process of joining two surfaces or edges together with a fastener so as to close an aperture, opening, or wound or join tissues. The fastener is usually a suture such as a thread of material (either polymeric or natural), gut, wire or the like. The term fastener as used herein also includes clamps, studs, hasps, catches, hooks, rivets, staples, snaps, stitches, VELCROC, buttons, and other coupling members.

As shown in FIG. **1**, a tissue suturing device **101** may be provided to close openings in body tissues. The tissue suturing device **101** includes multiple different parts. These parts may be generally divided into three sections including a handle section **192**, a substantially rigid intermediate section **191**, and a flexible elongated section **190**. Each section may include different sub-parts that are each designed to provide an intended portion of functionality.

The handle section **192** of the tissue suturing device **101** includes a hand grip **110** and rotatable handle portion **109**R. The hand grip and rotatable handle portion allow a physician or other user to hold and manipulate the tissue suturing device **101**. For example, the physician can hold on to the hand grip **110** and the rotatable handle portion **109**R when inserting or withdrawing the tissue suturing device from a body lumen. The handle section **192** also includes an actuating member **109**N which is mechanically linked to the needles **115** (FIGS. **4A-5**) in the elongated member **113**. When the handle **109**N is pulled, the mechanical link to the needles is actuated and the needles are drawn from the distal end **113**D of the elongated member **113** toward the proximal end **113**P of the elongated member **113**. As will be shown further in regard to FIGS. **2** and **3**, the handle **109**N is mechanically linked to a support holster **121** which holds the needles within the sheath **105**. When the handle **109**N is pulled toward the user, the support holster moves, along with the needles, through the sheath **105** and toward the handle.

The substantially rigid intermediate section **191** extends from the rotatable handle portion **109**R to the needle guide **106**. This intermediate section includes a barrel portion **108** which routes the needles **115** through the barrel and out toward the handle portion **192**. The needles **115** carry sutures **112** which are used to close openings in the tissue. The needles extend from the needle guide **106** through any intervening tissue toward the barrel portion **108**. The barrel portion captures the needles and routes them through an opening **124** toward the user. The substantially rigid intermediate section **191** also includes elongated subsection **107** which spans a tissue gap. This tissue gap comprises the tissue area through which the elongated subsection is inserted. The elongated subsection allows for the tissue suturing device **101** to be inserted transapically into the heart or into other bodily tissues. In some embodiments, the elongated subsection **107** may allow a user to insert the device transapically and perform a percutaneous closure of the left ventricle of the heart. This embodiment will be explained in greater detail below.

The flexible elongated portion **190** of the tissue suturing device **101** includes the needles **115** (shown in FIGS. **2-5**), a guidewire port for advancing the device along a guidewire **114** (shown in FIG. **2**) and a flexible outer sheath **105**. The flexible elongated portion **190** may be inserted entirely into the body lumen using the guidewire to advance the device. Once the tissue suturing device has been inserted into the vascular tissue, the guidewire can be removed by the operator. The sheath **105** of the elongated member **113** supports various internal structures including the needle holder **102** (FIG. **1**). The flexibility of the elongated portion allows the elongated portion to be inserted in a variety of different types and sizes of tissues, including into arteries (such as the femoral artery) and into the heart.

The needle holder **102** of the flexible elongated portion **190** may be configured to hold one or more needles within needle lumens **119** which are axially aligned and spaced about the interior of the elongated member **113** (as shown in FIG. **5**). The needle support holster **121**, upon actuation of the handle **109**, may be advanced up the needle shaft **111** toward the proximal end **113**P of the elongated member **113**. As the needle support holster **121** is advanced, the needles **115** held by the needle support holster **121** are correspondingly advanced toward the needle shaft **111** in the handle **109**. The needles are withdrawn through the needle guide **106** toward the barrel portion **108**. As will be explained in greater detail with regard to FIG. **7**, the barrel portion **108** includes two semi-circular openings **160** that receive the needles **115**, even in cases where the needles **115** are drawn through relatively large tissue gaps.

Thus, the flexible elongated portion **190** houses the needles **115** which will be drawn toward the handle **109** of the tissue

suturing device **101**. The needles **115** are withdrawn along needle guide **106** and across the tissue gap covered by elongated subsection **107** toward the barrel portion **108**. While being advanced from the needle guide **106** to the barrel portion **108**, the needles may exhibit a tendency to deflect or travel away from the tissue suturing device **101**. For example, in cases where the tissue suturing device **101** is inserted transapically into the left ventricle of the heart, the tissue suturing device will be inserted through body tissue that is thicker and/or tougher than the body tissue typically involved in a femoral arteriotomy. For instance, the tissue gap in a transapical insertion may be 1-5 cm. In a femoral arteriotomy, a tissue suturing device is placed through skin and muscle tissue in the leg, and ultimately through the femoral artery. In a transapical insertion, the tissue suturing device is inserted near or through the ribcage toward the heart. This tissue near the ribcage and heart is often fibrous and tough, and may cause the needles to deflect and travel away from the tissue suturing device. Accordingly, larger, semi-circular openings **160** are provided in the barrel portion **108** to capture the needles **115** as they approach the handle portion **109**.

Thus, to compensate for the thicker, more fibrous tissue through which the tissue suturing device **101** will be inserted, a tissue suturing device with a substantially rigid elongated subsection **107** is provided. The elongated subsection **107** provides sufficient space between the needle guides **106** and the needle-receiving barrel portion to allow transapical insertion of the device **101**. The needles **115** are drawn through the tissue and across the tissue gap provided by the elongated subsection **107**. The elongated subsection **107** is specifically designed to provide sufficient space between the needles **115** and the barrel portion **108** to allow transapical insertion of the elongated member **113**. This is show in greater detail in FIGS. **2-4**. It should be noted that although the tissue suturing device is usable for transapical insertion into a heart ventricle, it will be appreciated that the tissue suturing device **101** can be readily adapted for use with punctures made to other hollow body organs and lumens. It may, however, be necessary to modify the dimensions and other particular aspects of the tissue suturing device to accommodate the different usage environments.

Referring now to FIGS. **2**, **4**A, **4**B, and **5**, a tissue suturing device **101** is provided which is suitable for suturing and sealing of a percutaneous vascular puncture site (particularly those made transapically to the left ventricle of the heart), the tissue suturing device **101** having an alternate handle illustrated in phantom. The tissue suturing device **101** comprises an elongated member **113** and a needle shaft **111**. The elongated member **113** includes a guide tip **123** at its distal end of the substantially rigid intermediate section **191**. The guide tip includes a plurality of guide channels **125** which receive the proximal ends of needles **115**. The needles **115**, as illustrated, comprise a sharpened tip section **115**A and an elongated shank portion **122**, but may also be manufactured as an integral piece. The shank portion **122** may be sufficiently long so that the needles may be pushed from their butt end by a support holster **121** fixedly attached to the needle shaft **111**. By withdrawing the handle **109**N (FIG. **1** or FIG. **2**), the mechanically linked support holster **121** is also withdrawn toward the user, carrying the needles **115** and pushing the needles through the intervening tissue. The needles may be withdrawn until they enter the barrel portion **108** and exit through the barrel opening **124**.

The elongated member **113** further includes a plurality of needle lumens **119** which are axially aligned and spaced about the periphery of the elongated member. As shown in FIGS. **4**B and **5**, the needles **115** are designed to enter the distal ends of the lumens **119** as the needles are advanced proximally relative to the elongated member **113**. A flexible needle sheath (channel guide) **105** is attached to the guide tip **123** of the elongated member **113**. The central lumen of the needle sheath **105** receives a support holster **121** attached to the distal end of the needle shaft **111**, as well as the needles **115**. The butts of the needles **115** are removably received within the support holster **121**. The sheath **105** is designed to be sufficiently long to permit the needles to extend at least 5 cm beyond the distal end of elongated subsection **107** and into the barrel portion **108**.

Prior to use, the suture applying device **101** will be in the configuration illustrated in FIGS. **1** and **4**A. That is, the needle shaft **111** will be distally positioned within the elongated member **113** and needle sheath **105**. In particular, the tips of needles **115**A will lie just at the guide tip **123** so that they may be easily advanced through the vascular tissue of the heart, as well as any surrounding tissue. That is, the tips of the needles **115**A will be generally retracted within the guide tip **123**. A length of suture **112** is attached to the proximal tips **115**A of opposed pairs of needles **115**, with the connecting suture being stored within side lumens **126** extending axially along the exterior of the needle sheath **105**.

As best observed in FIGS. **4**A, **4**B and **5**, the suture **112** extending between one pair of opposed needles is received in a first of the side lumens **126**, while the suture extending between the other pair of opposed needles is received in the second of the side lumens **126**. In some embodiments, the sutures **112** may be stored in the lumens **119** of the elongated member **113** (and thus eliminate the need for side lumens **126**). The use of side lumens **126** may simplify feeding of the suture as the needles **115** are withdrawn.

After the guide tip **123** has been passed through the puncture site to be sutured, the needles may then be drawn proximally forward through the tissue to be sutured by drawing proximally on handle **109** at the proximal end of needle shaft **111**. Methods described herein for suturing an opening in a body lumen will now be described in more detail with reference to FIGS. **2-4**.

The situation following an interventional or other vascular procedure, where the attending physician is satisfied that the puncture site may be sealed, is illustrated in FIG. **2**. The device **101** may then be introduced over a guidewire **114**, as illustrated in FIG. **2**, and optionally through a support sheath **170**. The needles **115** and sutures **112** mostly encased by flexible needle sheath **105**, will be fully advanced into the artery or ventricle FA past the puncture site A. The handle **109**N may then be partially withdrawn proximally to expose the needle lumens **119** (as shown in FIGS. **1**, **4**A and **4**B).

The handle **109**N will then be drawn proximally outward relative to the elongated member **113**, causing the needles **115** to pass through the superficial wall of the artery/ventricle FA and into the needle lumens **119**, as illustrated in FIGS. **2** and **4**B. The handle **109**N may continue to be drawn proximally (i.e., outward from the patient) in order to continue to pull the needle shaft **111** through the elongated member **113**. Such movement of the needle shaft **111**, in turn, continues to draw the needles **115** outward through the lumens **125** of the elongated member **113** until the tips of the needles are exposed.

As mentioned above, the needles **115** are drawn from out of needle lumens **125** and through any intervening tissue. The tissue may be thick and fibrous, as is the case when the tissue suturing device is inserted transapically into the heart. The device's elongated subsection **107** provides sufficient rigidity and stiffness for insertion through and placement in the thick and fibrous tissue. It is across this elongated subsection **107** and through this tissue that the needles **115** are withdrawn. In

some cases, the needles **115** may deflect or drift while traveling through this tissue. Upon reaching the outer surface of the tissue, the needles may be guided into the semicircular openings **160** of the barrel portion **108**. The needles will thus carry their attached sutures **112** through the tissue, across the elongated subsection **107**, and through the barrel portion **108**. The sutures can then be grasped by the user and drawn out until the sutures are available to the user. The elongated member **113** may then be withdrawn from the support sheath **170**, leaving a portion of the needle sheath **105** still in the puncture site A to maintain hemostasis. The suture can then be tied and the knot pushed back down to the puncture site A. The knot will then only be tightened when the needle sheath is finally withdrawn from the puncture site A.

It can be seen that the guide tip **123** deflects the needles radially outward so that the pattern of four needles engages the arterial or ventrical wall in an approximately square pattern. These needles are then captured by the barrel portion **108**. As shown in FIG. **7**, the barrel portion captures the needles **115** traveling toward the handle **109** (FIG. **1**). The needles **115** enter the distal end of the barrel portion **108** through one of two semi-circular openings **160** (in some cases, there may be more or fewer openings, and the openings may be in shapes other than semi-circles). The outer surface at the proximal end of the barrel portion **108** includes a hole **124** connected to the semi-circular openings **160** through which the needles **115** are withdrawn. As such, the openings **160** direct the needles on a narrower trajectory toward the handle **109** of the suturing apparatus. The needles are drawn across the elongated subsection **107** in order to reach the barrel portion **108**. The elongated subsection **107** may be a predefined length, and may be specifically designed for the tissue though which the elongated member **113** is to be inserted.

For instance, as mentioned above, when the suturing device **101** is transapically inserted into the left ventricle of the heart, the elongated subsection **107** may comprise a specific length (e.g. within the range of 1-5 cm) for that type and/or thickness of tissue. Other types of insertion may necessitate use of a longer or shorter elongated subsection **107**. In some cases, the diameter of the barrel portion **108** may be proportional to the thickness of the tissue (i.e. the tissue gap). Thus, in cases where the tissue gap is longer (e.g. within the range of 4-5 cm) and the needles are more prone to drift, the barrel portion **108** may be larger. Conversely, in cases where the tissue gap is shorter (e.g. within the range of 1-2 cm) and the needles are less prone to drift, the barrel portion **108** may be smaller in diameter.

In specific cases where the body lumen suturing device is inserted into the left ventricle of the heart transapically, and implemented to suture an opening in the left ventricle of the heart, the elongated portion **113** of the suturing apparatus **101** may be advanced through the body lumen opening so that the needle lumens **106** are entirely within the body lumen **150**. The elongated member **113** of suturing apparatus **101** may be advanced in this manner until it is substantially aligned with the interior wall of the body lumen. One or more pledgets **116** stored at the proximal end of the needle lumens **106** in the elongated member **113** may be placed between the needle ends and the interior wall of the body lumen (as shown in FIG. **6**C). The needles **115**A/**115**B and attached sutures **112**A/**112**B are withdrawn through holes **118** in the pledget(s) **116**. As such, the pledgets remain in contact with the interior wall of the body lumen **150**, protecting the interior wall from forces applied to the sutures. The handle **109** may then be actuated to withdraw the needles **115** carrying the sutures **112** along the needle lumens **106**, through the interior wall of the body lumen **150**, and out through the opening **124** of the barrel portion **108**. After the sutures are tied and the knots advanced back through the support sheath **170**, the resulting pattern of tied suture will appear as in FIG. **8** when viewed towards adventitial surface of the body.

Turning now to another embodiment, the tissue suturing apparatus **101** may further be designed to implement pledgets. As used herein, a pledget may refer to an absorbent pad or other cloth- or cotton-like material for absorbing bodily fluids. In some cases, the pledgets may be fabricated using biocompatible and/or absorbable materials, and may be used accordingly in different applications. For instance, pledgets may be placed interior to or exterior to a body lumen. Accordingly, a pledget may be placed inside an arterial wall, outside an arterial wall, or elsewhere in the body. In embodiments where pledgets are used in ventricles of the heart, the pledgets may protect the inner ventricle from cutting of the tissue by knot advancement, tying or by other causes. The pledgets may be stored at the end of the proximal end of the needle lumens **106**. The sutures **112**A/**112**B may be routed through holes the pledgets. These holes are large enough not to restrict suture travel. The pledgets may be held in place by crimp ring **104**. These concepts will be explained below with regard to FIGS. **6**A-**6**D.

FIG. **6**A illustrates a zoomed-in view of the proximal end of the needle lumens **106**, and the distal end of the elongated subsection **107**. Needles **115**A and **115**B are shown still within the sheath **105** of the elongated member **113**. Corresponding sutures **112**A and **112**B are attached to needles **115**A and **115**B. In some cases, the sutures may be of differing colors. For instance, suture **112**A may be colored green, while suture **112**B is colored white. The sutures may be drawn through a hole **118** in pledget **116**. The pledget may be held in place by crimp ring **104** which extends around the elongated member **113**.

As mentioned previously, the pledgets may be used both interior to and exterior to a vascular or arterial wall. Accordingly, FIG. **6**B illustrates an embodiment where the pledget **116** is placed on the interior side of a body lumen (e.g. tissue **150**). The sutures are threaded through the hole **118** in the pledget, and then through the tissue **150** as they are drawn toward the barrel portion **108** of the suturing apparatus. In this position, the pledget can alleviate bleeding in the vascular wall, and help to maintain hemostasis. Although shown with four needles **115** and two sutures, it should be noted that substantially any number of needles and/or sutures may be used in different scenarios. In some cases, it may be beneficial to have more or fewer needles and/or sutures. Accordingly, the suturing apparatus may be adapted (or remanufactured) to be used in these cases.

Thus, as shown in FIG. **6**C, the sutures **112**A/**112**B held by the needles **115** are threaded through the pledget **116**, which is located between the sutures and the interior wall of the body lumen **150**. In some cases, as shown in FIG. **6**D, a second, different pledget may be placed in addition to (or as an alternative to) the pledget placed on the interior side of the body lumen (pledget **116**B). Pledget **116**A may be placed on the outside of the body lumen, and may function to alleviate bleeding on the outer part of the vascular wall. The exterior pledget (**116**A) may, like the interior pledget **116**B, be threaded with sutures **112**A and **112**B. These sutures may be drawn through the pledget(s) and out through the puncture site (PS). Thus, in FIG. **6**D, the sutures **112**A/**112**B held by the needles **115** are threaded through the interior pledget **116**B within the body lumen. The sutures **112**A/**112**B are also threaded through the exterior pledget **116**A which is exterior to the body lumen **150**, such that the exterior pledget **116**A is

located between the exterior wall of the body lumen and the barrel portion **108** of the apparatus **101**. The pledgets are stored at the proximal end **113**P of the needle lumens **106** in the elongated member **113**, and are held in place by a crimp ring **104** configured to hold the pledgets in place at the proximal end of the needle lumens **106** in the elongated member until they are withdrawn along with the sutures and the needles toward the barrel portion **108**.

A pledget **116** includes slits in various locations. The slits may be placed on the outer edge of the pledget in order to allow a suture to be slid into place (as opposed to being threaded through a hole in the pledget). The pledget may have two slits on opposite sides. Each slit may have two sutures through it. Substantially any number of sutures and/or slits may be used. The sutures may be slid through the slits and wrapped underneath the pledget. The ends of the sutures **112**A and **112**B may come out of the top surface of the pledget. The pledget slits may be sewn or otherwise fastened shut, resulting in sewn edges. The edges may be sewn after the sutures have been slid into place. The slits thus allow the sutures to be slid into place on the pledget, while the sewn edges prevent the sutures from coming out of place.

These slits and sewn edges may be configured in different arrangements. A pledget **116** may include crossing sutures **112**A and **112**B. The sutures may be slid into place using the respective slits. The sutures may extend out of the slits toward the user and/or toward the tissue suturing device. The sutures may be held in place within the slits with the sewn edges. As with the pledgets described above, the pledgets can be held in place in the tissue suturing device **101** using crimp ring **104**. Or, alternatively, the pledgets can be held in place by the sutures themselves. For example, if the sutures are crossed behind the suture, the pledget may be drawn up next to the tissue suturing device with the sutures holding the pledget in place. The sutures may be slid into place through slits, and may be aligned next to each other vertically. The top ends of the sutures **112**A and **112**B are then available for the user or device.

Accordingly, methods, systems and apparatuses are provided for suturing body lumens. A predefined tissue gap may be implemented to provide mechanisms for inserting the suturing device transapically into the left ventricle of the heart. Moreover, pledgets may be positioned within the suturing device for implementation on the exterior and interior walls of the body lumen. The placement of these pledgets may reduce blood loss and may assist in maintaining hemostasis.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

We claim:

1. An apparatus for suturing a body lumen, the apparatus comprising:

a flexible elongated member having a proximal end, a distal end, and a plurality of needle lumens extending from the proximal end toward the distal end, wherein the flexible elongated member comprises an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion comprising corresponding needle lumens on the proximal end of the elongated member, the elongated subsection providing sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member, the barrel portion comprising an outer surface and a distal surface extending transversely to a longitudinal axis of the flexible elongated member, the distal surface including one or more semi-circular openings;

a plurality of needles disposed within and advanceable from the plurality of needle lumens in the flexible elongated member across the elongated subsection, through the one or more semi-circular openings, to one or more corresponding needle lumens in the barrel portion; and

a handle disposed at the proximal end of the elongated member, the handle being operable to retract one or more of the plurality of needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end, the barrel portion including a barrel opening through the outer surface of the barrel portion connected to the semi-circular openings through which the needles are withdrawn.

2. The apparatus of claim **1**, further comprising a first pledget.

3. The apparatus of claim **2**, wherein the first pledget is located within the body lumen.

4. The apparatus of claim **3**, wherein sutures held by the needles are threaded through the first pledget, wherein the first pledget is located between the suture and the interior wall of the body lumen.

5. The apparatus of claim **4**, further comprising a second pledget located exterior to the body lumen.

6. The apparatus of claim **5**, wherein sutures held by the needles are threaded through the first pledget within the body lumen, wherein the first pledget is located between the suture and the interior wall of the body lumen, and wherein the sutures are further threaded through the second pledget exterior to the body lumen, wherein the second pledget is located between the exterior wall of the body lumen and the barrel portion of the apparatus.

7. The apparatus of claim **4**, wherein the pledgets are stored at the proximal end of the needle lumens in the elongated member.

8. The apparatus of claim **7**, wherein the elongated member comprises a crimp ring configured to hold the pledgets in place at the proximal end of the needle lumens in the elongated member.

9. The apparatus of claim **4**, wherein at least one of the pledgets includes slits on one or more outer edges of the pledget through which the sutures are each pulled into appropriate positions on the pledget.

10. The apparatus of claim **9**, wherein one or more of the pledget slits are sewn together on the outer edge of the slit.

11. The apparatus of claim **10**, wherein a sewn edge of the pledget slit prevents the sutures from sliding out of the pledget.

12. The apparatus of claim **1**, wherein the elongated subsection spans a predefined tissue gap length.

13. The apparatus of claim **7**, wherein a diameter of the barrel portion is proportional to the tissue gap.

14. A method for suturing an opening in a body lumen, the body lumen being accessed in a transapical manner, the method comprising:

providing a body lumen suturing device, the body lumen suturing device comprising:

a flexible elongated member having a proximal end, a distal end, and a plurality of needle lumens extending from the proximal end toward the distal end, wherein the flexible elongated member comprises an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion

comprising corresponding needle lumens on the proximal end of the elongated member, the elongated subsection providing sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member, the barrel portion comprising a distal surface extending transversely to a longitudinal axis of the flexible elongated member and an outer surface, the distal surface including one or more semi-circular openings, the barrel portion including a barrel opening through the outer surface of the barrel portion connected to the semi-circular openings,

a plurality of needles disposed within and advanceable from the plurality of needle lumens in the flexible elongated member across the elongated subsection, through the one or more semi-circular openings, to one or more corresponding needle lumens in the barrel portion; and

a handle disposed at the proximal end of the elongated member, the handle being operable to retract one or more of the plurality of needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end;

advancing the elongated member through the body lumen opening such that the needle lumens are entirely within the body lumen and the elongated subsection is substantially aligned with the interior wall of the body lumen; and

actuating the handle to withdraw the needles carrying the sutures along the needle lumens of the elongate member, through the interior wall of the body lumen, across the elongated subsection, enter the one or more semi-circular openings and further through the barrel opening, and out through the corresponding needle lumens in the barrel portion.

15. The method of claim **14**, wherein the body lumen suturing device is inserted into the left ventricle of the heart transapically, and implemented to suture an opening in the left ventricle of the heart.

16. The method of claim **15**, wherein one or more pledgets stored at the proximal end of the needle lumens in the elongated member are placed between the needle ends and the interior wall of the body lumen.

17. The method of claim **16**, wherein the needles and attached sutures are withdrawn through holes in the pledgets, such that the pledgets remain in contact with the interior wall of the body lumen, protecting the interior wall from forces applied to the sutures.

18. A body lumen suturing device comprising the following:

a flexible elongated member having a proximal end, a distal end, and a plurality of needle lumens extending from the proximal end toward the distal end, wherein the flexible elongated member comprises an elongated subsection spanning from the end of the needle lumens in the elongated member to a barrel portion comprising corresponding needle lumens on the proximal end of the elongated member, the elongated subsection providing sufficient space between the needles and the barrel portion to allow transapical insertion of the elongated member, the barrel portion comprising an outer surface and a distal surface extending transversely to a longitudinal axis of the flexible elongated member, the distal surface including one or more semi-circular openings, wherein the elongated member comprises a crimp ring configured to hold pledgets in place at the proximal end of the needle lumens in the elongated member;

a plurality of needles disposed within and advanceable from the plurality of needle lumens in the flexible elongated member across the elongated subsection, through the one or more semi-circular openings, to one or more corresponding needle lumens in the barrel portion;

one or more pledgets stored at the proximal end of the needle lumens in the elongated member, wherein the pledgets include one or more holes through which the sutures are pulled; and

a handle disposed at the proximal end of the elongated member, the handle being operable to retract one or more of the plurality of needles through the needle lumens of the elongated member across the elongated subsection toward the handle at the proximal end, the barrel portion including a barrel opening through the outer surface of the barrel portion connected to the semi-circular openings through which the needles are withdrawn.

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